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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,404	05/21/2001	Douglas T. Dieterich	144002-2001	8918

20999 7590 09/09/2002  
FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/862,404	DIETERICH, DOUGLAS T.
	Examiner Regina M. DeBerry	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 09 October 2001 .

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

    1. Certified copies of the priority documents have been received.

    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .

    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .      6) Other: \_\_\_\_\_ .

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn in part to a method for treating hepatitis C comprising administering ribavirin (RBV), or RBV and interferon-alpha (IFN), wherein the improvement comprises administering a vector that expresses erythropoietin (EPO) *in vivo*, classified in class 514, subclass 44.
  - II. Claims 1, 8-12, drawn in part to a method for treating hepatitis C comprising administering RBV or RBV and IFN-alpha, wherein the improvement comprises administering EPO, classified in class 514, subclass 2.
  - III. Claims 2 and 3, drawn to a method for treating RBV or RBV and IFN-alpha induced anemia comprising administering EPO, classified in class 514, subclass 2.
  - IV. Claims 4-7, drawn to a method for treating hepatitis C and for treating RBV or RBV and IFN-alpha induced anemia comprising administering EPO, classified in class 514, subclass 2.
  - V. Claims 13-15, drawn to the kit, classified in class 424, subclass 85.1.
  - VI. Claim 16, drawn to the composition comprising EPO and IFN, classified in class 530, subclass 350.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-IV are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. In addition, the Groups are drawn to treating different patient populations. Invention I requires treatment of hepatitis C comprising administering a DNA vector, which is a structurally and functionally distinct element from the other groups. Invention II requires treatment of hepatitis C comprising administering RBV and IFN-alpha which are structurally and functionally distinct elements from the other groups. Invention III requires treatment of RBV or RBV and IFN-alpha induced anemia comprising administering EPO which is a distinct element from the other groups and which achieves a different goal. Invention IV requires treatment of hepatitis C and RBV or RBV and IFN-alpha induced anemia comprising administering EPO, which is a distinct element from the other groups and which achieves a different goal. Therefore, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

Inventions V and I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups I-IV do not require the packaged kit of Group V.

Inventions VI and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group VI can be used in the methods of Groups I-IV, but can also be used in a different process of using such as making antibodies.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups V and VI are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The composition of Group VI does not require the packaged kit in Group V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

*RMD*

RMD  
September 6, 2002